II. THE CLAIMS

Claim 1. (Original) A controlled release oral solid dosage form for the reduction of serum cholesterol levels in humans comprising a drug comprising an alkyl ester of hydroxy substituted naphthalenes and a controlled release carrier in an amount effective to provide a controlled release of the drug, the dosage form providing a mean time to maximum plasma concentration (T_{max}) of the drug which occurs at about 10 to about 32 hours after oral administration to human patients, the dosage form providing a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

Claim 2. (Original) The controlled release oral solid dosage form of claim 1, which includes an amount of a controlled-release carrier for said drug effective to provide a substantially complete release of said drug in about 4 to 30 hours in vitro in a Type 2 USP 23 dissolution apparatus in 2% sodium lauryl sulfate, pH buffer to 7.0 at 37° C and 50rpm.

Claim 3. (Original) The controlled release oral solid dosage form of claim 1, which provides a dissolution of from about 0% to about 25% drug released after 2 hours; from about 40% to about 85% drug released after 6 hours; and not less than about 75% drug released after 16 hours, when measured in vitro in a Type 2 USP 23 dissolution apparatus in 2% sodium lauryl sulfate, pH buffer to 7.0 at 37° C and 50rpm.

Claim 4. (Original) The controlled release oral solid dosage form of claim 1, which provides a dissolution of from about 0% to about 20% drug released after 2 hours; from about 50% to about 80% drug released after 6 hours; and not less than about 80% drug released after 16 hours, when measured in vitro in a Type 2 USP 23 dissolution apparatus in 2% sodium lauryl sulfate, pH buffer to 7.0 at 37°C and 50rpm.

Claim 5. (Original) The controlled release oral solid dosage form of claim 1, which provides a dissolution of from about 10% to about 15% drug released after 2 hours; from about 65% to about 75% drug released after 6 hours; and not less than about 79% drug released after 16 hours, when measured in vitro in a Type 2 USP 23 dissolution apparatus in 2% sodium lauryl sulfate, pH buffer to 7.0 at 37°C and 50rpm.

Claim 6. (Original) The controlled release oral solid dosage form of claim 1, which provides a mean time to maximum plasma concentration about 14 to about 24 hours after oral administration.

Claim 7. (Original) The controlled release dosage form of claim 1, wherein the drug is lovastatin, said dosage form providing a mean maximum plasma concentration (C_{max}) of lovastatin from about 1 ng/ml to about 8 ng/ml, based on a 40 mg dose of lovastatin, after administration to human patients.

Claim 8. (Original) The controlled release dosage form of claim 1, wherein the drug is lovastatin, said dosage form providing a maximum plasma concentration (C_{max}) of the drug of from about 3 ng/ml to about 4 ng/ml (based on a 40 mg dose of lovastatin), after administration to human patients.

Claim 9. (Original) The controlled release dosage form of claim 1, wherein the drug is selected from the group consisting of lovastatin, a derivative of lovastatin, an active metabolite of lovastatin, mevastatin, pravastatin, simvastatin, and mixtures thereof.

Claim 10. (Original) The controlled release dosage form of claim 1, wherein the drug is lovastatin.

Claim 11. (Original) The controlled release dosage form of claim 1, wherein the drug is lovastatin in an amount of from about 10 to about 80 mg.

Claim 12. (Original) The controlled release dosage form of claim 1, wherein the drug is lovastatin, and the dosage form provides a mean $AUC_{0\text{-}48hr}$ of lovastatin from about 15 to about 90 ng·hr/ml.

Claim 13. (Original)The controlled release dosage form of claim 1, wherein the drug is lovastatin, and the dosage form provides a mean $AUC_{0\text{-}48hr}$ of lovastatin from about 34 to about 77 ng·hr/ml.

Claims 14-17. (Cancelled)

Claim 18. (Original) The controlled release dosage form of claim 1, wherein the drug is lovastatin and the dosage form provides a mean $AUC_{0\text{-}48hr}$ of lovastatin acid from about 9.96 to about 132.54 ng·hr/ml.

Claim 19. (Original) The controlled release dosage form of claim 1, wherein the drug is lovastatin and the dosage form provides a mean $AUC_{0\text{-}48hr}$ of lovastatin acid from about 47.5 to about 91.2 ng·hr/ml.

Claim 20. (Cancelled)

Claim 21. (Currently Amended) The controlled release dosage form of claim ~~20~~1, which provides a mean maximum plasma concentration (C_{max}) of total HMG-CoA Reductase Inhibitors from about 4.7 ng/ml to about 25.4 ng/ml, based on a 40 mg dose of lovastatin.

Claim 22. (Currently Amended) The controlled release dosage form of claim ~~20~~1, which provides a mean maximum plasma concentration (C_{max}) of total HMG-CoA Reductase Inhibitors from about 10.5 ng/ml to about 17.3 ng/ml, based on a 40 mg dose of lovastatin.

Claims 23-24. (Cancelled)

Claim 25. (Currently Amended) The controlled release dosage form of claim ~~23~~1, which provides a mean maximum plasma concentration (C_{max}) of active HMG-CoA Reductase Inhibitors from about 2.1 ng/ml to about 22.5 ng/ml, based on a 40 mg dose of lovastatin.

Claim 26. (Currently Amended) The controlled release dosage form of claim ~~23~~1, which provides a mean maximum plasma concentration (C_{max}) of active HMG-CoA Reductase Inhibitors from about 6.4 ng/ml to about 13.4 ng/ml.

Claim 27. (Original) The controlled release oral solid dosage form of claim 1, which provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 11 to about 32 hours after oral administration of a single dose of said drug to human patients in the morning.

Claim 28. (Original) The controlled release oral solid dosage form of claim 27, wherein the dosage form provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 16 to about 32 hours after oral administration of a single dose after breakfast (in the fed state).

Claim 29. (Original) The controlled release oral solid dosage form of claim 28, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of the drug from about 1.5 ng/ml to about 4.5 ng/ml, based on a 40 mg dose of lovastatin, after oral administration of a single dose after breakfast (in the fed state).

Claim 30. (Cancelled)

Claim 31. (Original) The controlled release oral solid dosage form of claim 1, which when administered in the morning in the fed state, provides a mean time to maximum plasma concentration (T_{max}) which occurs at from about 22 to about 26 hours after administration.

Claim 32. (Original) The controlled release dosage form of claim 1, wherein the drug is lovastatin, said dosage form providing a mean maximum plasma concentration (C_{max}) of lovastatin from about 1.5 ng/ml to about 7.1 ng/ml, based on a 40 mg dose of lovastatin, after administration to human patients.

Claim 33. (Original) The controlled release oral solid dosage form of claim 1, which provides a mean time to maximum plasma concentration (T_{max}) at about 10.4 to about 20.6 hours after oral administration to human patients after administration of a single dose of said drug at dinner time.

Claim 34. (Original) The controlled release oral solid dosage form of claim 33, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug from about 1.9 ng/ml to about 4.4 ng/ml, based on a 40 mg dose of lovastatin.

Claim 35. (Original) The controlled release oral solid dosage form of claim 33, which provides a mean time to maximum plasma concentration (T_{max}) at about 13.5 to about 17.5 hours after oral administration at dinner time.

Claim 36. (Original) The controlled release oral solid dosage form of claim 35, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of lovastatin of about 3 ng/ml, based on a 40 mg dose of lovastatin.

Claim 37. (Original) The controlled release oral solid dosage form of claim 1, which dosage form provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 10 to about 23.2 hours after oral administration to a human patient after administration of a single dose of said drug to human patients at bedtime.

Claim 38. (Original) The controlled release oral solid dosage form of claim 37, which dosage form provides a mean time to maximum plasma concentration (T_{max}) at about 14.2 to about 16.9 hours after oral administration of a single dose of said drug to human patients at bedtime.

Claim 39. (Original) The controlled release oral solid dosage form of claim 1, which dosage form provides a mean time to maximum plasma concentration (T_{max}) at about 10 to about 22 hours at steady-state after oral administration to human patients at bedtime.

Claim 40. (Original) The controlled release oral solid dosage form of claim 39, which dosage form provides a mean time to maximum plasma concentration (T_{max}) at about 12 to about 16 hours at steady-state after oral administration to human patients at bedtime.

Claim 41. (Original) The controlled release oral solid dosage form of claim 39, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug from about 1 ng/ml to about 8 ng/ml, based on a 40 mg dose of lovastatin.

Claim 42. (Original) The controlled release oral solid dosage form of claim 40, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of the drug of about 4 ng/ml, based on a 40 mg dose of lovastatin, after oral administration of a single dose at bedtime.

Claim 43. (Original) The controlled release oral solid dosage form of claim 1, wherein the drug is selected from the group consisting of lovastatin, a derivative of lovastatin, an active metabolite of lovastatin, and mixtures thereof.

Claim 44. (Original) The controlled release oral solid dosage form of claim 3, which provides a mean time to maximum plasma concentration about 14 to about 24 hours after oral administration.

Claim 45. (Original) The controlled release dosage form of claim 44, wherein the drug is lovastatin, said dosage form providing a mean maximum plasma concentration (C_{max}) of lovastatin from about 1.5 ng/ml to about 7.1 ng/ml, based on a 40 mg dose of lovastatin, after administration to human patients.

Claim 46. (Original) The controlled release dosage form of claim 44, wherein the drug is lovastatin, said dosage form providing a maximum plasma concentration (C_{max}) of the drug of from about 3 ng/ml to about 4 ng/ml (based on a 40 mg dose of lovastatin), after administration to human patients.

Claim 47. (Original) The controlled release oral solid dosage form of claim 44, which achieves an accumulation of lovastatin and its latent and active metabolites at steady-state conditions of about 1.4- to about 2-fold the levels attained by immediate release lovastatin administered once daily.

Claim 48. (Original) A method for reducing serum cholesterol levels in humans, comprising orally administering a drug comprising an alkyl ester of hydroxy substituted naphthalenes in a controlled release oral solid dosage form which provides a mean time to maximum plasma concentration (T_{max}) of the drug which occurs at about 10 to about 32 hours after oral administration of said dosage form to human patients.

Claim 49. (Original) The method of claim 48, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of lovastatin from about 1 ng/ml to about 8 ng/ml, based on a 40 mg dose of lovastatin, after administration to human patients.

Claim 50. (Original) The method of claim 48, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of lovastatin from about 1.5 ng/ml to about 7.1 ng/ml, based on a 40 mg dose of lovastatin, after administration to human patients

Claim 51. (Original) A method for reducing serum cholesterol levels in humans, comprising orally administering a drug comprising an alkyl ester of hydroxy substituted naphthalenes in a controlled release oral solid dosage form to human patients in the morning, which dosage form provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 11 to about 32 hours after oral administration to human patients.

Claim 52. (Original) The method of claim 51, wherein the drug is lovastatin.

Claim 53. (Original) The method of claim 51, wherein the T_{max} occurs at about 16.3 to about 24 hours after administration.

Claim 54. (Original) The method of claim 51, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug from about 1.5 ng/ml to about 6.9 ng/ml, based on a 40 mg dose of lovastatin.

Claims 55-56. (Cancelled)

Claim 57. (Original) The method of claim 51, further comprising administering the dosage form in the morning in the fed state, such that the time to maximum plasma concentration (T_{max}) occurs from about 22 to about 26 hours after administration.

Claim 58. (Original) A method for reducing serum cholesterol levels in humans, comprising orally administering a drug comprising an alkyl ester of hydroxy substituted naphthalenes in a controlled release oral solid dosage form to human patients at dinner time, which dosage form provides a mean time to maximum plasma concentration (T_{max}) at about 10.4 to about 20.6 hours after oral administration of a single dose of lovastatin to a population of human patients.

Claim 59. (Original) The method of claim 58, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug from about 1.9 ng/ml to about 4.4 ng/ml, based on a 40 mg dose of lovastatin.

Claim 60. (Original) The method of claim 58, wherein the mean time to maximum plasma concentration (T_{max}) occurs at from about 13.5 hours to about 17.5 hours after oral administration.

Claim 61. (Original) The method of claim 60, wherein the drug is lovastatin, and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug of about 3 ng/ml, based on a 40 mg dose of lovastatin.

Claim 62. (Original) A method for reducing serum cholesterol levels in humans, comprising orally administering a drug comprising an alkyl ester of hydroxy substituted naphthalenes in a controlled release oral solid dosage form to human patients at bedtime, which dosage form provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 10 to about 23.2 hours after oral administration.

Claim 63. (Original) The method of claim 62, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug from about 1 ng/ml to about 8 ng/ml, based on a 40 mg dose of lovastatin.

Claim 64. (Original) The method of claim 62, wherein the dosage form provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 14.2 to about 16.9 hours after oral administration of a single dose.

Claim 65. (Original) The method of claim 62, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of the drug of about 4 ng/ml, based on a 40 mg dose of lovastatin, after oral administration of a single dose.

Claim 66. (Original) The method of claim 62, wherein said T_{max} occurs at about 10 to about 22 hours after oral administration to human patients at steady-state.

Claim 67. (Original) The method of claim 62, wherein said T_{max} occurs at about 12 to about 16 hours after oral administration.

Claim 68. (Original) The method of claim 66, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug from about 3 ng/ml to about 8 ng/ml, based on a 40 mg dose of lovastatin at steady-state.

Claim 69. (Original) The method of claim 66, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug of about 5.5 ng/ml.

Claim 70. (Original) A method for improving the dose-response relationship achieved via the administration of a statin drug orally administered in immediate release form, comprising orally administering the statin in a controlled release dosage form which provides a mean time to

maximum plasma concentration (T_{max}) of the statin drug which occurs at about 10 to about 32 hours after oral administration to human patients.

Claim 71. (Original) A method for providing increased systemic bioavailability of lovastatin, while at the same time not increasing the bioavailability of lovastatin acid, active or total inhibitors compared to an immediate release reference standard form of lovastatin, comprising preparing a controlled release oral solid dosage form of lovastatin which comprises a therapeutically effective amount of lovastatin and a sufficient amount of a controlled release carrier such that the controlled release dosage form provides a dissolution of from about 0% to about 25% lovastatin released after 2 hours; from about 40% to about 85% lovastatin released after 6 hours; and not less than about 75% lovastatin released after 16 hours, when measured in vitro in a Type 2 USP 23 dissolution apparatus in 2% sodium lauryl sulfate, pH buffer to 7.0 at 37°C and 50rpm, and such that said dosage form provides a mean time to maximum plasma concentration (T_{max}) of said lovastatin from about 10 to about 32 hours after oral administration to human patients, and administering said dosage form to human patients on a once-a-day basis.

Claims 72-75. (Cancelled)

Claim 76. (Previously Presented) A controlled release oral solid dosage form for the reduction of serum cholesterol levels in humans comprising a therapeutically effective amount of lovastatin and a controlled release carrier in an amount effective to provide a controlled release of the lovastatin when the dosage form is orally administered, the dosage form providing a mean time to maximum plasma concentration (T_{max}) of the lovastatin which occurs at about 9.8 to about 18.8 (14.3 ± 4.5) hours after oral administration to human patients at bedtime.

Claim 77. (Previously presented) A controlled release oral solid dosage form for the reduction of serum cholesterol levels in humans comprising a therapeutically effective amount of lovastatin and a controlled release carrier in an amount effective to provide a controlled release of the

lovastatin when the dosage form is orally administered, the dosage form providing a mean time to maximum plasma concentration (T_{max}) of the lovastatin which occurs at about 10.6 to about 23.2 (16.9 ± 6.3) hours after oral administration to human patients at bedtime.

Claim 78. (Previously Presented) A method for reducing serum cholesterol levels in humans, comprising orally administering a therapeutically effective amount of lovastatin in a controlled release oral solid dosage form to human patients at bedtime, which dosage form provides a mean time to maximum plasma concentration (T_{max}) of the lovastatin which occurs at about 9.8 to about 18.8 (14.3 ± 4.5) hours after oral administration to human patients at bedtime.

Claim 79. (Previously Presented) A method for reducing serum cholesterol levels in humans, comprising orally administering a therapeutically effective amount of lovastatin in a controlled release oral solid dosage form to human patients at bedtime, which dosage form provides a mean time to maximum plasma concentration (T_{max}) of the lovastatin which occurs at about 10.6 to about 23.2 (16.9 ± 6.3) hours after oral administration to human patients at bedtime.

Claim 80. (Previously Presented) A controlled release oral solid dosage form for the reduction of serum cholesterol levels in humans comprising a therapeutically effective amount of lovastatin and a controlled release carrier in an amount effective to provide a controlled release of the lovastatin when the dosage form is orally administered, the dosage form providing a mean time to maximum plasma concentration (T_{max}) of the lovastatin which occurs at about 10.4 to about 20.6 (15.5 ± 5.1) hours after oral administration to human patients with the evening meal.

Claim 81. (Previously Presented) A method for reducing serum cholesterol levels in humans, comprising orally administering a therapeutically effective amount of lovastatin in a controlled release oral solid dosage form to human patients at bedtime, which dosage form provides a mean time to maximum plasma concentration (T_{max}) of the lovastatin which occurs at about 10.4 to about 20.6 (15.5 ± 5.1) hours after oral administration to human patients with the evening meal.